IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
v.	)	Case No. 4:13-cv-00449-BCW
	)	
VITAS HOSPICE SERVICES, L.L.C., *et al*.,	)	
	)	
Defendants.	)	

UNITED STATES OF AMERICA	)	
Ex rel. CHARLES GONZALES,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:13-cv-00344-BCW
	)	
VITAS HEALTHCARE CORP., *et al*.,	)	
	)	
Defendants.	)	

UNITED STATES OF AMERICA	)	
Ex rel. BARBARA URICK,	)	
	)	
Plaintiffs,	)	
v.	)	Case No. 4:13-cv-000563-BCW
	)	
VITAS HME SOLUTIONS, INC., *et al*.,	)	
	)	
Defendants.	)	

UNITED STATES OF AMERICA and STATE OF ILLINOIS, ex. rel. LAURA SPOTTISWOOD, Plaintiffs, v. CHEMED CORPORATION, f/d/b/a VITAS HOSPICE SERVICES, L.L.C., *et al.*, Defendants.	)	Case No. 4:13-cv-00505-BCW

DEFENDANTS' SUGGESTIONS IN SUPPORT OF THEIR MOTION TO DISMISS THE UNITED STATES' FIRST AMENDED COMPLAINT AND COMPLAINT IN INTERVENTION

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Defendants Vitas Hospice Services, L.L.C., Chemed Corporation, Vitas Healthcare Corporation, Vitas Healthcare Corporation of California, Vitas Healthcare Corporation of Illinois, Vitas Healthcare Corporation of Florida, Vitas Healthcare Corporation of Ohio, Vitas Healthcare Corporation Atlantic, Vitas Healthcare Corporation Midwest, Vitas Healthcare Corporation of Georgia, and Vitas Healthcare of Texas, L.P. (collectively "Defendants"), move to dismiss this action.

The United States' First Amended Complaint and Complaint in Intervention ("Amended Complaint")1 fails to meet the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) because, after taking the allegations as true and drawing all reasonable inferences, it does not sufficiently plead the "who, what, where, when, and how" of Defendants' purported fraud. Further, it fails to state a claim on which relief may be granted because it contains no specific allegations that Defendants' claims for Medicare payments were materially false or fraudulent. The government's common law claims suffer from the same defects. Accordingly, the Amended Complaint should be dismissed with prejudice in its entirety.

SUMMARY OF ARGUMENT

The government's Amended Complaint seeks to make a False Claims Act ("FCA") case out of medical judgment – and not just any medical judgment, but medical judgment about the prognosis for terminal illness. Such prognoses are the key statutory requirement for eligibility for Medicare's hospice benefit. The Centers for Medicare and Medicaid Services ("CMS"), which administers the hospice benefit, recognizes the complexity involved in making such determinations, repeatedly acknowledging that they are not a "perfect science." 78 Fed. Reg. 27823, 27832 (May 10, 2013); 70 Fed. Reg. 70532, 70534, 70538, 70542 (Nov. 22, 2005). Since

1 Case No. 4:13-cv-00449 [Doc. 56]; Case No. 4:13-cv-00344 [Doc. 27]; Case No. 4:13-cv-00563 [Doc. 99]; Case No. 4:13-cv-00505 [Doc. 80].

the hospice benefit became available in 1983, CMS has pushed for increasing awareness and utilization of the benefit, leading to a growing percentage of beneficiaries with non-cancer diagnoses that are even more difficult to prognose.2 78 Fed. Reg. 27823-01 (May 10, 2013). CMS and its contractors recognize that patients who do not meet all the guidelines may still be eligible for payment under the hospice benefit.

Despite an existing and well utilized administrative process to review claims and consider medical judgment against the context of existing guidelines, the government is now attempting to use the FCA to regulate prognosis or level of care decisions. The government is trying to do so retroactively, reaching back over a decade to recoup an untold number of claims nationwide and recasting valid medical differences of opinion as "false" claims subject to treble damages and penalties. See United States ex rel. Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002) (Failing to enforce a strict interpretation of the prerequisite to payment requirement would "improperly permit qui tam plaintiffs to supplant regulatory discretion granted to [Health and Human Services] under the Social Security Act, essentially turning a discretionary denial of payment into a mandatory penalty for failure to meet Medicare requirements.").

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2 Strong policy and economic arguments support CMS' push for broad utilization of the hospice benefit. Most Americans – well over 70 percent – prefer to die at home. Despite this overwhelming preference to be in familiar surroundings with easier access by family and friends, less than a quarter do.

> This disconnect has ruinous economic costs. About a quarter of Medicare's $550 billion budget pays for medical treatment in the last year of life. Almost a third of Medicare patients have surgery in their last year of life, and nearly one in five in their last month of life. In their last year of life, one-third to one-half of Medicare patients spend time in an intensive care unit, where 10 days of futile flailing can cost as much as $323,000. Medical overtreatment costs the U.S. health care system an estimated $158 billion to $226 billion per year.

Katy Butler, A Full Life to the End, The Wall Street Journal, Sept. 7, 2013, at C1.

These flaws completely undermine the theory of the Amended Complaint. In legal terms, the Amended Complaint fails to comply with Rule 9(b)'s particularity requirement, fails to state any cognizable claims for relief under Rule 12(b)(6), and is barred in part by the FCA's applicable statute of limitations. In pleading terms, the Amended Complaint fails because it imposes a retrospective framework on inherently subjective, necessarily prospective prognosis and level of care determinations. The Amended Complaint treats guidelines as rules, ignoring the discretionary nature of those guidelines, which themselves counsel against an inflexible application of their terms because patients not meeting set criteria may still be suffering from a terminal illness. The Amended Complaint also ignores that the guidelines set out other criteria that may support the patients' terminal prognoses. The Amended Complaint points to vaguely defined "business practices" or "marketing tactics" as leading to the submission of false or fraudulent claims. As to the claims themselves, the government imposes its own post hoc review of thirteen patients' medical records to challenge the medical judgments and eligibility decisions of, in each circumstance, two physicians – including the patients' own attending physicians (assuming they have one)3 – or to dispute the level of care provided to patients requiring continuous home care. The Amended Complaint fails to identify any individuals involved in admitting, certifying, or changing the level of service for these 13 patients; the details regarding the allegedly false statements or certifications made in connection with these patients; or the details regarding the allegedly false claims submitted for services provided to these patients.

In addition to the Rule 9(b) pleading deficiencies, the government has failed to allege necessary elements to establish a claim under Rule 12(b)(6), including that any regulation or guidance was material or a condition of payment, that any such regulation or guidance was

3 If a patient does not have an attending physician, then no certification from the attending physician is required. 42 C.F.R. § 418.22(c)(1)(ii) (2011).

violated, or that anyone acted with the requisite scienter to be liable under the FCA. Most deadly to the Amended Complaint is that payment of claims that do not meet the guidelines is discretionary – in other words, the guidelines are, in fact, only guidelines. These are not mere pleading deficiencies that can be overcome by the Court's leave to amend the complaint a second time. These are legal deficiencies that are fatal to the theory of "falsity" set forth in the Amended Complaint.

These pleading failures must also be viewed in the context of the government's investigation and the surfeit of information to which the government has had access. The government has been investigating Vitas for patient eligibility and recertification issues since 2005. During this time period, Vitas has produced millions of pages of documents, including policies, training manuals, and patient files in relation to hospice programs in Florida, Texas, California, Missouri, and other locations. Last year, the government took the depositions of six current and former Vitas employees and interviewed numerous others. At the government's request, Vitas extended the statute of limitations period *fifteen* times – time that the government used to continue its investigation. Despite spending over eight years on this case, and despite truckloads of documents and other information, the government has failed to meet the basic pleading requirements of the FCA.

Nor is the government without guidance on FCA pleading requirements in this particular investigation. The first two subpoenas that the government issued were in connection with a *qui tam* complaint filed in the Southern District of Florida in June 2004 regarding three of Vitas' Florida programs. Broadly stated, the complaint alleged Vitas knowingly falsely recertified patients as eligible for hospice benefits, when those patients were ineligible because they did not have a prognosis of six months or less to live. Following the government's decision not to

intervene "at this time," after three years of investigation by the government and literally hundreds of thousands of pages of patient files and other documents produced by Vitas, Vitas moved to dismiss because the allegations – focused, like the Amended Complaint, on the asserted business "environment" at Vitas – were insufficient to state a claim, and the complaint was dismissed with prejudice by the United States District Court for the Southern District of Florida on July 25, 2007. The Court of Appeals for the Eleventh Circuit affirmed the dismissal on all bases on November 3, 2008 and issued the mandate on December 2, 2008. Barys ex rel. United States v. Vitas Healthcare Corp., et al., Case No. 07-13720 (11th Cir. Dec. 2, 2008).

For these reasons, the Amended Complaint must be dismissed with prejudice.

BACKGROUND

A. The Hospice Medicare Benefit.

Hospice care is a Medicare benefit designed to provide terminally ill individuals with comfort, pain relief, and emotional and spiritual support, as opposed to curative care for the terminal illness, and is provided by an interdisciplinary team. Am. Compl. ¶¶ 23, 39; 42 C.F.R. §§ 418.3, 418.56, 418.70, 418.72 (2008); 42 C.F.R. § 418.76 (2009); 42 C.F.R. § 418.64 (2012); 48 Fed. Reg. 56008 (Dec. 16, 1983). Hospice services may be provided in several venues, including the patient's home, a nursing home, or within a hospital. The goal of the benefit, however, is to offer "the opportunity to die with dignity in the comfort of one's home rather than in an institutional setting." 78 Fed. Reg. 27823, 27826 (May 10, 2013) (internal citation omitted).

1. Eligibility for Hospice Care.

To be eligible for hospice, a patient must be terminally ill and must forego curative treatment in exchange for the hospice benefit. Am. Compl. ¶ 28; 42 C.F.R. § 418.20 (2012); 42

C.F.R. § 418.24 (2006). A patient is terminally ill if a certifying physician determines in his/her medical judgment that the patient has a "medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course."[4] Am. Compl. ¶ 27; 42 C.F.R. § 418.3; 42 C.F.R. § 418.22 (2011). Initial certifications of a terminal illness may be made only on the basis of the "clinical judgment" of the two physicians authorized to do so by statute and regulation: (1) the hospice's medical director or another hospice physician, and (2) the patient's "attending physician," the physician taking care of the patient prior to the election of hospice. Am. Compl. ¶ 38; 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.22.

There are no objective standards for physicians' certifications of terminal illness under the Medicare statute and its implementing regulations. Instead, the regulatory scheme relies upon the physicians' clinical judgment to determine when patients are "terminally ill" and appropriate for hospice. 42 C.F.R. § 418.22; Medicare Benefit Policy Manual, Ch. 9, § 10. The government has repeatedly acknowledged that predicting life expectancy is not an "exact science" and that "[i]t is often not a single diagnosis that represents the terminal illness of the patient, but the combined effect of several conditions that makes the patient's condition terminal." 78 Fed. Reg. 27823, 27826 (May 10, 2013); 70 Fed. Reg. 70532, 70538 (Nov. 22, 2005).

Indeed, in making the determination, the hospice medical director is required to consider, not only the patient's diagnosis of terminal condition, but also the patient's "[o]ther health conditions, whether related or unrelated to the terminal condition," and "[c]urrent clinically relevant information supporting all diagnoses." 42 C.F.R. § 418.25(b) (2006). While Medicare

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[4] While a terminally ill patient must have a life expectancy of six months or less, there is no limit to the number of benefit periods available to a Medicare beneficiary. 42 C.F.R. § 418.21 (2006); 70 Fed. Reg. 70532, 70533-43 (Nov. 22, 2005).

does not pay for services or items "which are not reasonable and necessary for the palliation or management of terminal illness," 42 U.S.C. § 1395y(a)(1)(C), it is CMS' "general view that 'hospices are required to provide virtually all the care that is needed by terminally ill patients.'" 78 Fed. Reg. 27823, 27826 (May 10, 2013) (quoting 48 Fed. Reg. 56008, 56010 (Dec. 16, 1983)); see also 42 C.F.R. § 418.202(i) (2011) (The hospice benefit covers "any other service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions and for which payment may otherwise be made under Medicare."). "Therefore, unless there is clear evidence that a condition is unrelated to the terminal illness, all services would be considered related." 78 Fed. Reg. 27823, 27826-27 (May 10, 2013). This reduces the cost burden on CMS because hospice pays a fixed per diem. The inclusion of related services limits other payments.

CMS and Medicare Administrative Contractors ("MACs") like Palmetto, issue policy manuals, guidance, and local coverage determinations ("LCDs"), formerly local medical review policies ("LMRPs"), (collectively "the guidance") regarding their interpretations of the hospice regulations. Am. Compl. ¶¶ 34, 44-45. CMS has determined that none of this is binding or dispositive. 68 Fed. Reg. 63692, 63693 (Nov. 7, 2003) ("Under our claims appeals process, ALJs may consider, but are not bound by, LMRPs or LCDs. Thus, an ALJ may rule that Medicare payment is due on a particular item or service received by a beneficiary, based on the particular circumstances represented by the case, even if the contractor's [guidance] clearly prohibits payment for the particular service."); see also 42 C.F.R. § 405.1062(a) (2005). "Coverage of hospice care for patients not meeting the criteria in this policy may be denied. However, some patients may not meet the criteria, yet still be appropriate for hospice care . . . ." Ex. A (Palmetto GBA, LCD for Hospice – Liver Disease, L31536 (2011)) (emphasis added);

see also Ex. B (National Government Services, Inc., LCD for Hospice – Determining Terminal Status, L25678 (2009)) ("Some patients may not meet these guidelines, yet still have a life expectancy of six months or less. Coverage for these patients may be approved if documentation otherwise supporting a less than six-month life expectancy is provided.").

Although the regulations have changed during the time period covered by the Amended Complaint,[5] CMS has never required a physician's certification to include "specific clinical findings," as the government incorrectly alleges. Am. Compl. ¶ 33. In fact, CMS rejected and deleted the proposed use of the terms "specific" and "findings" in 2005. 70 Fed. Reg. 70532, 70543 (Nov. 22, 2005). The exacting documentation requirements that the government seeks to regulate through this lawsuit simply are not – and never have been – legally required.

2. Continuous Home Care.

Medicare reimburses for four types of care: (1) routine home care, (2) continuous home care, (3) inpatient respite care, and (4) general inpatient care. Am. Compl. ¶ 4; 42 C.F.R. § 418.302(b) (2009); Medicare Benefit Policy Manual, Ch. 9, § 40. The government refers to continuous home care as "crisis care" even though that term is not used in the regulations. Am. Compl. ¶ 5. Consistent with the goal of the hospice benefit, continuous home care is designed to keep the patient at home during periods "in which the individual requires continuous care [which is primarily nursing care] to achieve palliation or management of acute medical

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5 Prior to 2005, a physician's certification of "terminally ill" status had to contain a statement "that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course" and had to be filed in the medical records. 42 C.F.R. § 418.22(b) (2005). Effective November 22, 2005, CMS added a requirement that "[c]linical information and other documentation that support the medical prognosis" be filed in the record with the certification. 70 Fed. Reg. 70532, 70543 (Nov. 22, 2005). In August of 2009, CMS added a requirement to "include a brief narrative explanation of the clinical findings that supports a life expectancy of 6 months or less" with the certification and recertification forms. 42 C.F.R. § 418.22(b)(3) (2009).

symptoms." Am. Compl. ¶ 25; 42 C.F.R. §§ 418.204(a), 418.302(b)(2) (2009). CMS understands that "[i]f a patient's caregiver has been providing a skilled level of care for the patient and the caregiver is unwilling or unable to continue providing care, this may precipitate a period of crisis because the skills of a nurse may be needed to replace the services that had been provided by the caregiver." Medicare Benefit Policy Manual, Ch. 9, § 40.2.1. The name continuous care is somewhat of a misnomer because "care need not be continuous." Id. Rather, a minimum of 8 hours of care, consisting predominantly of nursing care, must be provided during a 24-hour period. Id. As CMS explains, "4 hours could be provided in the morning and another 4 hours in the evening." Id. As long as a patient's illness does not preclude him from doing so, there is nothing about continuous home care that prevents a patient from living out his or her remaining days to their fullest – receiving spiritual support from attending church, maintaining one's appearance and dignity by getting one's hair done, or enjoying leisure activities like bingo. See Am. Compl. ¶ 64; 70 Fed. Reg. 22394 (April 29, 2005) ("The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining in [their] home . . . ."). Indeed, the very point of continuous home care is to avoid more costly institutional settings and to be with friends and family at the end of life.

3. Submission of Claims.

Hospice providers submit claims for reimbursement of hospice services using the CMS-1450 form.6 Am. Compl. ¶ 47; Ex. C. By signing the form, the hospice incorporates the certifications and verifications listed on the back page, including that the:

6 The CMS-1450 is a standard, uniform bill ("UB") for reimbursement of medical services used by healthcare providers, also known as the UB-92, and was replaced by the UB-04 on May 23, 2007. Compare Ex. C, with Ex. D (CMS Form-1450, revised 2007).

- "Physician's certifications and re-certifications, if required by contract or Federal regulations, are on file;" and that
- "This claim, to the best of my knowledge, is correct and complete and is in conformance with the Civil Rights Act of 1964 as amended. Records adequately disclosing services will be maintained and necessary information will be furnished to such governmental agencies as required by applicable law."

Ex. C; see also Am. Compl. ¶ 52.

LEGAL STANDARDS

A. The False Claims Act.

The FCA imposes liability on any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or (2) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim. United States ex rel. Miller v. Weston Ed., Inc., 2012 WL 6190307, at *2 (W.D. Mo. Dec. 12, 2012) (citing 31 U.S.C. § 3729(a)(1)(A)-(B)).[7] The FCA is not "an all-purpose antifraud statute," Allison Engine Co., Inc. v. United States ex rel. Sanders, 553 U.S. 662, 672 (2008), and the "FCA is not concerned with regulatory noncompliance." United States ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791, 795 (8th Cir. 2011). Because liability under the FCA turns on false claims rather than fraudulent conduct, an FCA complaint must, at its most basic, "show that a claim for payment from the government was made and that the claim was 'false or fraudulent.'" Miller, 2012 WL 6190307, at *2 (quoting United States ex rel. Rabushka v. Crane Co., 122 F.3d 559, 563 (8th Cir. 1997)).

To give rise to FCA liability, regulatory noncompliance must be material to the government's payment decision. United States ex rel. Ketroser v. Mayo Foundation, et al., 2013

7 Congress amended the FCA in May of 2009, re-designating 31 U.S.C. § 3729(a)(1) as 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(2) as 31 U.S.C. § 3729(a)(1)(B). United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 303 (3d Cir. 2011) (citing Pub. L. No. 111–21, 123 Stat. 1617 (2009)).

WL 4733986, at *5 (8th Cir. Sept. 4, 2013); Vigil, 639 F.3d at 796; Miller, 2012 WL 6190307, at *5-6. In the Medicare context, materiality turns on whether the alleged noncompliance involved conditions of payment rather than conditions of participation. Ketroser, 2013 WL 4733986, at *5; Vigil, 639 F.3d at 796; United States ex rel. Onnen v. Sioux Falls Ind. Sch. Dist., 688 F.3d 410, 414–15 (8th Cir. 2012); Miller, 2012 WL 6190307, at *6.

B. Rule 9(b).

Because the FCA is an anti-fraud statute, complaints alleging violations of the FCA must comply with Federal Rule of Civil Procedure 9(b)'s particularity requirement by pleading "such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006); see also United States ex rel. Kinney v. Stoltz, 327 F.3d 671, 674-75 (8th Cir. 2003) (FCA claims must comply with Rule 9(b)). Rule 9(b)'s threshold requirement demands that an FCA complaint identify the actual false claims submitted to the government. The government cannot simply allege a general theme, but must identify with particularity the false claims that were actually submitted. See Joshi, 441 F.3d at 557 (affirming dismissal under Rule 9(b) for failure to allege the details of the fraudulent claims allegedly submitted to the government). "Without sufficient allegations of materially false claims, an FCA complaint fails to state a claim on which relief may be granted." Vigil, 639 F.3d at 796.

C. Rule 12(b)(6).

A complaint must be dismissed where, as here, it fails to state a claim upon which relief can be granted. Under Federal Rule of Civil Procedure 12(b)(6),

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has

> facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.

Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (internal citations and quotation marks omitted); Vigil, 639 F.3d at 796 (citing Iqbal, 556 U.S. at 678). The "[t]wo working principles" underlying this standard are: (1) "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions," and (2) "only a complaint that states a plausible claim for relief survives a motion to dismiss" and "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]-that the pleader is entitled to relief.'" Iqbal, 556 U.S. at 678-79 (quoting Fed. R. Civ. P. 8(a)(2)). The Court is "free to ignore legal conclusions, unsupported conclusions, unwarranted inferences and sweeping legal conclusions cast in the form of factual allegations." Farm Credit Servs. of Am. v. American State Bank, 339 F.3d 764, 767 (8th Cir. 2003) (internal citation and quotation marks omitted). "When deciding a motion to dismiss, a court may consider the complaint and documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading." Kushner v. Beverly Enter., Inc., 317 F.3d 820, 831 (8th Cir. 2003) (internal citation and quotation marks omitted).

ARGUMENT

I. THE AMENDED COMPLAINT FAILS TO SATISFY RULE 9(b)'S PLEADING REQUIREMENTS.

The Amended Complaint advances a theory that vague "business practices" and "marketing tactics," plus involvement in program auditing or reviews, by unidentified

individuals, led to the submission of false claims in violation of the FCA because unidentified individuals disregarded whether the services were appropriate. In violation of the clear command of Rule 9(b), the Amended Complaint does not plead the who, what, when, where, or how of the various entities' roles in the alleged wrongdoing. United States ex rel. Roop v. Hypoguard USA, Inc., 559 F.3d 818, 822 (8th Cir. 2009); Joshi, 441 F.3d at 556-57. This follows years of one-sided discovery. The Amended Complaint does not allege "who" purportedly established or was involved in the business practices or marketing tactics, including the goal setting; who was involved in making the determinations about patient admissions and levels of care; or who was involved in the claims preparation and submissions process. It similarly provides insufficient allegations about the contents of the allegedly false or fraudulent claims—the "what." Although the Amended Complaint identifies a handful of patient examples that it alleges were inappropriate because the medical record, in the government's view, does not support certain disease-specific guidelines, it provides insufficient details to make it plausible that these were false claims. The Amended Complaint provides absolutely no factual details connecting "how" the alleged business practices or marketing tactics caused those purportedly inappropriate determinations or more importantly caused the submission of actual false claims or certifications. Finally, the Amended Complaint fails to allege adequately the "when" or "where" of the alleged conduct, cursorily alleging instead a general time period from at least 2002 to the present against all 51 hospice programs without sufficient supporting factual allegations. Because the Amended Complaint does not satisfy Rule 9(b), it must be dismissed.

A. The Amended Complaint Fails To Specify "Who."

The United States inappropriately relies on collective allegations against distinct corporate entities and fails to specify who purportedly did what in perpetrating the alleged fraud. Such

pleadings flunk Rule 9(b)'s pleading requirements and warrant dismissal. See, e.g., United States ex rel. Branhan v. Mercy Health Sys., 1999 WL 618018, at 9* (6th Cir. Aug. 5, 1999) (prohibiting a relator from "indiscriminately grouping all of the individual defendants into one wrongdoing monolith") (internal citation and quotation marks omitted); Sears v. Likens, 912 F.2d 889, 893 (7th Cir. 1990); Unimobil 84, Inc. v. Spurney, 797 F.2d 214, 217 (5th Cir. 1986).[8]

The Amended Complaint fails to plead with particularity any facts showing what role each Defendant allegedly played in the supposed misconduct. Rather, it regularly clumps the parent Chemed together with Vitas in its allegations, see, e.g., Am. Compl. ¶¶ 9, 54-57, 159, or collectively refers to the Defendants as Vitas. Id. ¶ 1. The Amended Complaint does not identify which Defendant submitted claims and which Defendant purportedly took actions that caused the submission of allegedly false claims. Courts regularly dismiss complaints for this sort of deficient pleading under Rule 9(b). See, e.g., Talton v. Unisource Network Services, Inc., 2001 WL 1035732, at *6 (N.D. Ill. Sept. 10, 2001) (dismissing complaint under Rule 9(b) for vaguely attributing a fraudulent statement to a group of defendants without specifying what was said, by whom, or when); Zvunca v. Motor Coach Indus. Int'l, Inc., 2009 WL 483867, at *4–5 (N.D. Ill. Feb. 26, 2009) (held that complaint was insufficient under Rule 9(b) for failing to

8 A complaint that "merely includes vague allegations" of conduct by "'Defendants' without specificity or explanation" does not satisfy Rule 9(b). Bradley v. Phillips Petroleum Co., 527 F. Supp. 2d 625, 655 (S.D. Tex. 2007) (citing Unimobil 84 Inc., 797 F.2d at 217), aff'd, 337 F. App'x 397 (5th Cir. 2009). Particularity of each defendant's role in the alleged fraud is critical in multiple defendant lawsuits for a number of reasons, including to ensure each defendant has fair notice of the charges against it and to protect against guilt by association. See United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 190 (5th Cir. 2009) (citing Melder v. Morris, 27 F.3d 1097, 1100 (5th Cir. 1994)) (stating Rule 9(b)'s objective is ensuring the complaint provides defendants with fair notice, protects them from harm to their reputation and goodwill, reduces the number of strike suits, and prevents plaintiffs from filing baseless claims and then attempting to discover unknown wrongs).

allege the specific identity of the speaker of any fraudulent statement and, instead, lumping all defendants together in the allegations).9

The Amended Complaint likewise fails to plead with particularity the identity of any individuals at any of the Defendant corporations responsible for any actual false claims submitted or caused to be submitted to the government. Notably, the government conspicuously omits the identity of certifying physicians involved in enrolling or certifying ineligible patients for hospice care or continuous home care, which is particularly fatal because decisions about hospice admissions, recertifications, and levels of care are made only by physicians, including some independent attending physicians. Additionally, the Amended Complaint fails to identify corporate representatives who were engaged in fraud. Pleading the "who" is particularly important because a corporation may not be held liable on some general allegations that someone may have known something or done something or on some collective amalgam of information possessed by different individuals. Kushner, 317 F.3d at 827-830; Detroit Gen. Retirement Sys. v. Medtronic, Inc., 621 F.3d 800, 808 (8th Cir. 2010).

B. The Amended Complaint Fails To Specify "What."

The Amended Complaint fails to describe – with particularity or plausibility – the actual content of any allegedly false representation. Rather than identifying any falsity or misrepresentation, the Amended Complaint simply alleges in conclusory terms that Vitas' claims, submitted on CMS-1450 forms, were "false" because patients purportedly were not eligible for

9 See also Bruhl v. Pricewaterhouse Coopers Int'l, 2007 WL 997362, at *3-4 (S.D. Fla. Mar. 27, 2007) (dismissing complaint under Rule 9(b) because it lumped a parent and a purported subsidiary together and referred to them throughout the complaint interchangeably as the "Citgo Defendants"); Beshears v. Provident Life & Acc. Ins. Co., 2007 WL 1438738, at *2 (D. Ariz. May 15, 2007) (dismissing complaint under Rule 9(b) where it named a parent and subsidiary company as defendants and did not describe what conduct was taken by each defendant).

hospice care benefits or the level of care provided based on the government's view that a handful of patient records did not squarely fit within the unspecified guidance. See Am. Compl. ¶¶ 68, 163. Merely labeling a claim as "false" does not make it so; instead, Rule 9(b)'s heightened pleading standard requires FCA plaintiffs to specify exactly what makes them false. As the Eighth Circuit has made clear, to plead fraud with particularity a complaint must allege "details relating to the making, using, or submitting of any Certifications," including alleging with particularity or plausibility why any "alleged regulatory violations were material to the government's decision to pay each of the various types of claims submitted" under the Medicare hospice benefit program. Vigil, 639 F.3d at 799. "Merely alleging why the Certifications were false is insufficient." Id.

The Amended Complaint's theory of liability – that the submission of a claim for Medicare hospice benefits is necessarily "false" for FCA purposes, if the hospice provider's recordkeeping is not completely consistent with the guidance – is without merit. For the 13 patients identified in the Amended Complaint, it does not allege that any of the information identified on CMS-1450, such as the patient's identity, principal diagnosis, date of certification or recertification, or level of care, was misrepresented or false. The Amended Complaint also does not allege with any particularity that an employee of any Defendant falsely certified (1) that "[p]hysician's certifications and re-certifications, if required by contract or Federal regulations, are on file" knowing they were not on file or (2) that, to the best of that unidentified certifying individual's knowledge, he or she did not believe "[t]his claim is correct and complete" yet nonetheless certified the claim as correct and complete. Ex. C; Am. Compl. ¶ 52. Finally, the government does not allege with any particularity or plausibility that one or more of the Defendants did not maintain "[r]ecords adequately disclosing services" or did not furnish

"necessary information . . . to such governmental agencies as required by applicable law." Ex. C; Am. Compl. ¶ 52.

The government's allegation on this crucial issue amounts to one conclusory paragraph that "Chemed and Vitas falsely certified . . . that Vitas's claims were 'correct and complete' and that Vitas maintained patient medical records in compliance with the certification requirements of 42 C.F.R. § 418.22." Am. Compl. ¶ 163. The government provides no other allegation detailing what about the claim was incorrect or incomplete and repeatedly omits the "best of my knowledge" language from its recitation of the certification language. See id. ¶¶ 52, 163. Of course, the fact that the certification includes this subjective qualifier undercuts the plausibility of the government's theory of FCA liability based on its purportedly "objective" comparison of the patient's medical records to particular LCD or policy manual criteria. The government has not alleged with any particularity or plausibility that unidentified certifying individuals did not believe to the best of their knowledge that "[t]his claim was correct or complete." In fact, the Amended Complaint is devoid of even one allegation about the claims or certification process, even though the submission of a claim is "the sine qua non of a False Claims Act violation." United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002).

Additionally, the Amended Complaint's allegations do not specify even a single instance when a claim was submitted for Medicare payment without a physician certification of terminal illness for those patients. Nor does it address the other scenarios that the guidelines recognize where a patient may be eligible even if he or she does not meet the disease-specific criteria. 68 Fed. Reg. 63692, 63693 (Nov. 7, 2003); see also 42 C.F.R. § 405.1062(a). The Amended Complaint cursorily describes 13 patients' medical records, time periods during which they were on hospice with Vitas, amounts billed, and sometimes bill numbers. See generally, Am.

Compl. ¶¶ 79-158, 187-241. Even though eligibility for the Medicare hospice benefit is governed by physician certification of terminal illness, Am. Compl. ¶ 27, not a single allegation addresses the specific details of the physician certifications for these 13 patients. While the Amended Complaint suggests that certain individuals questioned whether patients were appropriate for hospice, Am. Compl. ¶¶ 173-77, those allegations are not tied in any way to specific patients or claims and do not at all undermine the validity of the certifications. There is no allegation that the hospice's medical director or another hospice physician improperly or falsely certified a given patient or ordered a higher level of care because of the alleged business or marketing practices. The Amended Complaint completely ignores that, as part of the admission's process, the patient's attending physician, employing his or her own independent medical judgment, arrived at the same determination concerning the patient's prognosis and eligibility for hospice.

For the examples of alleged ineligible patients, the government's allegations generally focus on one purported diagnosis and narrowly compare the patient's medical record to the disease-specific guidelines. For example, the government identifies examples of patients that have, at least in part, a diagnosis of a terminal illness based on heart disease. See, e.g., Am. Compl. ¶¶ 191-98, 217-22, 223-32. Although the disease-specific guidelines suggest that one of the factors that should be present is that the patient meets "the criteria for the New York Heart Association (NYHA) Class IV," the LCD also specifically states that:

> The word 'should' in the disease specific guidelines means that on medical review the guideline so identified will be given great weight in making a coverage determination. It does not mean, however, that meeting the guideline is required. The only requirement is that the documentation supports the beneficiary's prognosis of six months or less, if the illness runs its normal course.

Ex. B (emphasis added). The government's singular focus on this one factor ignores the non-disease specific factors as well as the discretionary nature of the guidelines.10 Id. (acknowledging that "[s]ome patients may not meet these guidelines, yet still have a life expectancy of six months or less"); 78 Fed. Reg. 27823, 27826 (May 10, 2013) (CMS stating that "[i]t is often not a single diagnosis that represents the terminal illness of the patient, but the combined effect of several conditions that makes the patient's condition terminal.").

Moreover, the government's allegations concerning continuous home care suffer from the same type of pleading defect. While the government simply asserts that 7 patients were not in acute medical crisis, it fails to provide sufficient allegations to support that claim. For example, the government acknowledges that the medical record for patient DT indicated that DT was "having symptoms of weakness, mental status changes, confusion and agitation;" it does not allege in any manner, however, that these symptoms were not acute or that management of these symptoms did not require "primarily nursing care." Am. Compl. ¶ 124. The government instead claims that the care did not involve "intensive nursing care" or "intensive palliative interventions" or only involved "low-dose and low-frequency" medications. Am. Compl. ¶¶ 124, 126. These are not required by the continuous home care regulations. Continuous home care involves periods of time "in which the individual requires continuous care [which is primarily nursing care] to achieve palliation or management of acute medical symptoms" to maintain the patient at home.11 Am. Compl. ¶ 25; 42 C.F.R. §§ 418.204(a), 418.302(b)(2). If

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10 The government's purported review of other patient records, such as those allegedly admitted for debility-type diagnoses, suffers for the same faulty reasoning. See, e.g., Am. Compl. ¶¶ 187-90, 210-16, 233-41.

11 The Amended Complaint alleges an instance where a medical doctor used the term "actively dying" in discussing continuous home care, which it suggests is "a term not used anywhere in the Medicare requirements." Am. Compl. ¶ 63; but see 70 Fed. Reg. 70532, 70540

the government is implying that the care was not "time intensive," the government does not allege that fewer than 8 hours of primarily nursing care was provided for any of the patients. Ex. E (Medicare Benefit Policy Manual, Ch. 9, § 40.4.1.1) ("Continuous care is not a highly specialized service, because while time intensive, it does not require highly specialized nursing skills.") (emphasis added). In other examples, the government suggests that management of other symptoms, such as "pain management" or "shortness of breath," should be addressed through routine home care. See Am. Compl. ¶¶ 92, 97-98, 107-08, 117.12 Again, the Amended Complaint lacks sufficient allegations to support these opinions and provides no particular allegations that primarily nursing services were not provided during a period of crisis in which a patient requires continuous care that is primarily nursing care to achieve palliation or management of acute medical symptoms. 42 C.F.R. §§ 418.204(a), 418.302(b)(2).

Furthermore, all that 42 C.F.R. § 418.22 requires in terms of recordkeeping is that the physician certification and, after November 22, 2005, "[c]linical information and other

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(Nov. 22, 2005). The government provides no particular allegations to infer anything inappropriate about the meaning of the doctor's reference to "actively dying," which is sometimes used to refer to the final hours or days of a person's life. In those final hours of life, some patients experience crises that may make continuous home care appropriate so that, consistent with the goals of the hospice benefit, the patient can die at home rather than an emergency room. See, e.g., Kathleen A. Moneymaker, Understanding the Dying Process: Transitions during Final Days to Hours, J. of Palliative Med., Vol. 8, No. 5, 1079 (2005) (discussing some of the changes when a loved one is "ACTIVELY dying" as including pain, muscle jerking, labored breathing, vomiting, and loss of bowel control), available at http://www.aahpm.org/pdf/dying.pdf. CMS similarly recognizes that "imminent death"—even though it is nowhere used in the Medicare requirements—may create a period of crisis during which continuous home care is appropriate. Ex. E (Medicare Benefit Policy Manual, Ch. 9, § 40.2.1.2, Symptom management/rapid deterioration/imminent death, Situation C).

12 Similarly, the government's allegations about patients going to church, having their hair done, or playing bingo not only belittle the dignity of the individual patients but also say nothing about their conditions or whether at least 8 hours of continuous home care was required and provided. Am. Compl. ¶ 64.

documentation that support the medical prognosis" be included in the patient's medical records. Specifically, it provides that "Hospice staff must—

> (1) Make an appropriate entry in the patient's medical record as soon as they receive an oral certification; and
> (2) File written certifications in the medical record."

Id. While the government may question whether the information adequately supports the prognosis, the government does not allege with any particularity or plausibility that this information was not included or that anyone did not believe it did not support the medical prognosis. Regardless, recordkeeping is a condition of participation, rather than a condition of payment, and the government does not, and indeed cannot, allege how a violation of these requirements would be a basis for FCA liability. Ketroser, 2013 WL 4733986, at *6; Vigil, 639 F.3d at 798-99; see also 42 C.F.R. § 418.104 (2008); Am. Compl. ¶ 48.

C. The Amended Complaint Fails To Specify "How."

Beyond the sheer lack of allegations concerning how any claims or certifications were false, the Amended Complaint makes no attempt to link the alleged violations to the alleged business and marketing practices. No particular allegations support the government's theory that the marketing materials, operational reviews, goals, or training led to alleged violations of the documentation requirements or certifications that the claim for any given patient was correct or complete. The government relies on nothing more than naked assertions, see, e.g., Am. Compl. ¶¶ 8, 56, 160, and provides no connection between the alleged business and marketing practices and the claims for the 13 cherry-picked patients that the government alleges were inappropriate for hospice or continuous home care. Courts around the country, including in this Circuit, routinely reject such pleading deficiencies. Vigil, 639 F.3d at 798 (upholding dismissal on 9(b) grounds where the complaint did "not identify any claim submitted . . . based upon loans

obtained as a result of Nelnet's alleged regulatory violations – prohibited inducements and fraudulent marketing practices. Nor does the Complaint allege how the false Certification was material to DOEd's decision to pay"); United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah, 472 F.3d 702, 727 (10th Cir. 2006) (allegations of schemes and wrongful activities that result in the submission of false claims fail to satisfy Rule 9(b) "unless such pleadings are 'linked to allegations, stated with particularity, of the actual false claims submitted to the government'") (internal citation omitted).13

For example, the government fails to explain how corresponding with hospice programs about operational statistics, such as operating margins in various programs, is problematic or anything more than sound business management, particularly given that the correspondence it references does not even support its exaggerated allegation that Vitas focused on utilization of continuous home care, particularly when utilization was allegedly low. Am. Compl. ¶ 60. Considering how labor intensive it is to provide continuous home care, it is unsurprising that a hospice would be interested in tracking margins, which is simply a measure of the difference between revenue and costs. As the correspondence shows, the lower margins were the result of inefficient staffing allocations, including incorrect skill mix, unfilled shifts, and excess overtime. Ex. F (E-mail from C. Garland to I. Viente (Jan. 18, 2007, 18:15 EST)).

The government's allegations about goal setting and the inference that it led to inappropriate patient admissions or levels of care is unsupported by any facts in the Amended

13 See Clausen, 290 F.3d at 1311 ("Rule 9(b)'s directive that 'the circumstances constituting fraud or mistake shall be stated with particularity' does not permit a False Claim Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government.") (internal citation omitted); United States ex rel. Lacy v. New Horizons, Inc., 348 F. App'x 421, 427 (10th Cir. 2009) (affirming dismissal of § 3729(a)(2) claim where plaintiff failed to "demonstrate the required link" between the alleged false or fraudulent conduct and an actual false or fraudulent claim).

Complaint. The government provides no allegations that the goals affected the clinical judgment of the certifying physicians. To the contrary, the government admits that bonuses tied to goals were paid only to "non-clinical staff." Am. Compl. ¶ 167; see also id. ¶ 66. The government's theory about goals depends entirely on unwarranted inferences that this Court is free to ignore. Farm Credit Servs. of Am., 339 F.3d at 767 (internal citation omitted).

Similarly, the government's suggestion that Vitas improperly and inaccurately marketed "intensive comfort care" services, Vitas' brand name for continuous home care, is also unfounded and does not permit any inferences about inappropriate conduct by any of the Defendants. Am. Compl. ¶¶ 58-59. The marketing material mentions the very things the government claims Vitas somehow fraudulently omitted, explaining that continuous home care is for "[s]hort-term, medically necessary symptom management" and is "provided in the home for acute symptom management." Ex. G (Vitas' Clinical Experts Manage Intensive Comfort Care (2007)). Moreover, the reference to symptoms causing distress to the patient or family is completely consistent with the government's own guidance for providing continuous home care. As the government explains, a stress that prevents a family member from providing skilled care to the patient may constitute a "period of crisis" for which continuous home care is appropriate. Ex. E (Medicare Benefit Policy Manual, Ch. 9, § 40.2.1) ("If a patient's caregiver has been providing a skilled level of care for the patient and the caregiver is unwilling or unable to continue providing care, this may precipitate a period of crisis because the skills of a nurse may be needed to replace the services that had been provided by the caregiver.") Another example provided by CMS cites a change in the patient's symptoms and the "patient's wife stat[ing] she is unable to provide any more care for her husband" as a situation that would require continuous home care. Id. The government fails to explain how Vitas' similar statement is misleading. Far

from providing adequate support for the government's theory, the actual documents on which the Amended Complaint purports to rely demonstrate that the government's allegations are unfounded and do not provide any reliable indicia of a purported fraudulent scheme.

Significantly, the Eleventh Circuit already once has dismissed similar allegations of false claims against Vitas for the Medicare hospice benefit based on supposedly improper business practices. Barys ex rel. United States v. Vitas Healthcare Corp., et al., 298 F. App'x 893, 895–97 (11th Cir. 2008). The Eleventh Circuit upheld the district court's dismissal because the allegations failed to provide a factual basis for questioning physician certifications of terminal illness and likewise failed to link the purported practices to any actual false claims submitted to the government. Id. at 896–97. Specifically, the court held that utilization of compensation programs to encourage high populations is insufficient to support an inference of fraud "without allegations of instances in which . . . administrators fraudulently re-certified patients . . . ." Id. at 896. For the reasons discussed above, the same result is required here.

D. The Amended Complaint Fails To Specify "When."

Rule 9(b) requires the government to set forth with particularity the date(s) of any allegedly fraudulent conduct. See United States ex rel. Bledsoe v. Community Health Systems, Inc., 342 F.3d 634, 643 (6th Cir. 2003) (dismissing complaint because it "failed to set forth dates as to the various FCA violations or any particulars as to the incidents of improper billing"). The Amended Complaint generally alleges that false claims were submitted or caused to be submitted to the government from at least 2002 through the present. Am. Compl. ¶ 9. Yet, the Amended Complaint lacks the necessary particularity or representative examples to support such sweeping assertions. The 13 patient examples in the Amended Complaint involve claims from no earlier than May 2005 and primarily involve the time period from 2006 to 2010. Only two

patients had hospice claims after 2010, and the government concedes that one of those patients died while receiving hospice in February 2012 (greatly undermining the plausibility of the government's allegation that he was ineligible). Am. Compl. ¶ 208. There is nothing about these patient examples that makes them representative of patients from other time periods. This is particularly important given that CMS changed its regulatory requirements concerning certification, effective November 22, 2005. Previously, the regulations did not require that "[c]linical information and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification." 70 Fed. Reg. 70532, 70543 (Nov. 22, 2005). Thus, the government's allegations concerning patient records after 2005 provide no reliable indicia concerning patient records prior to the regulatory change.

Not only does the government fail to allege any improper patients, much less purportedly false claims, from other time periods, it also fails to point to any allegedly improper conduct outside of a similar time period. For example, the alleged marketing materials, the correspondence about operational issues, and the internal audits—all entirely proper conduct—all relate to a narrower period from 2007 to 2010. Am. Compl. ¶¶ 60, 69-70, 178-80. The Amended Complaint provides no basis to plausibly infer that some business conduct occurring in 2007 or more recently began back in 2002. See United States ex rel. Woods v. North Ark. Reg'l Med. Ctr., 2006 WL 2583662, at *3-4 (W.D. Ark. Sept. 7, 2006) (finding that conclusory allegations involving a conspiracy to violate the AKS and FCA over a twelve-year time period based on information pertaining to a limited six-month period lacked the specificity required by Rule 9(b)); United States ex rel. Black v. Health & Hosp. Corp. of Marion Cnty., 2011 WL

1161737, at *14 (D. Md. Mar. 28, 2011) (dismissing lawsuit seeking to predicate alleged FCA violations from 2002 through 2009 on three documents from 2002).

E. The Amended Complaint Fails To Specify "Where."

Finally, the Amended Complaint fails to allege adequately where the allegedly false claims occurred. The Amended Complaint appears to allege a nationwide scheme involving 51 hospice programs in 18 states, Am. Compl. ¶ 18, but the patient examples are limited to merely 7 of those 51 programs. See generally Am. Compl. ¶¶ 78-158, 186-241. Of those 7 programs, the government relies on 4 examples from a single Texas program, which it acknowledges involved not only an administrative focused medical review, but also an internal review that led to 75-80 discharges, 3 examples from a California program, 2 examples from a Florida program, and 1 example each from 4 other programs. Id. Rather than provide any reliable indicia of some nationwide scheme, these allegations at best suggest an isolated problem in one program and an exception or two out of the thousands of patients served by each of the other programs. The government's allegations fail to provide the necessary particularity of "where" under Rule 9(b). See Corsello v. Lincare, Inc., 428 F.3d 1008, 1013 (11th Cir. 2005) (allegations that improper practices took place "everywhere [defendant] does business throughout the statutory time period" are too vague to comply with the rule).

Because the government fails to satisfy Rule 9(b)'s pleading standard, the Amended Complaint should be dismissed.

II. THE AMENDED COMPLAINT FAILS TO STATE ANY VIABLE CLAIMS FOR RELIEF.

The Amended Complaint also should be dismissed for failure to state a claim under 12(b)(6). The Amended Complaint does not allege sufficient factual allegations to make it possible, let alone plausible, that any Defendant should be liable for any purported misconduct

under the FCA. The government broadly alleges that an unspecified universe of claims submitted by Vitas for patients allegedly inappropriate for hospice, as well as claims for services for continuous home care, were rendered false or fraudulent because the Defendants disregarded federal regulations or CMS or MAC guidelines relating to the Medicare hospice benefit. Even if the government's allegations about these regulations and guidelines were correct as a matter of law, regulatory noncompliance alone is not sufficient to state a claim under the FCA. Rather, the government must allege, among other things: (1) that Medicare required compliance with those regulations or guidance as a prerequisite to payment, (2) that the Defendants failed to comply knowing them to be conditions of payment, and (3) that Defendants nonetheless submitted or caused to be submitted claims that impliedly or expressly represented that Vitas was in compliance. The government has failed to allege these elements with the necessary specificity and factual basis under the applicable pleading standards:

1) The government fails to allege that any of the regulations, LCDs, or policy manuals allegedly violated were material or conditions of payment; and

2) The government cannot make any plausible allegation that any Defendant violated or caused to be violated any such regulations.

Moreover, the Amended Complaint must be dismissed for the separate reason that it cannot plausibly allege that any Defendant had the requisite scienter to be held liable under the FCA. The government's claims therefore must be dismissed because the Amended Complaint fails to allege facts establishing a basis for relief, as required by Rule 12(b)(6).

A. The Amended Complaint Fails To Allege A Violation Of A Regulation, LCD, Or Policy Manual That Was Material Or A Condition Of Payment.

The government fails to allege any basis in fact or law to demonstrate that any of the regulations, LCDs, or policy manuals identified in the Amended Complaint is a condition of payment. The government attempts to allege FCA fraud through its allegations of Defendants'

purported violations of conditions of participation concerning medical recordkeeping, and supposed disregard of medical criteria identified in CMS policy manuals and Palmetto LCDs. Instead, to serve as a basis for an FCA claim, Medicare must require compliance with regulation or guidance as a prerequisite to payment. Vigil, 639 F.3d at 796; Miller, 2012 WL 6190307, at *2.

> To allow FCA suits to proceed where government payment of Medicare claims is not conditioned on perfect regulatory compliance - and where [CMS] may choose to waive administrative remedies, or impose a less drastic sanction than full denial of payment- would improperly permit qui tam plaintiffs to supplant the regulatory discretion granted to [CMS] under the Social Security Act, essentially turning a discretionary denial of payment remedy into a mandatory penalty for failure to meet Medicare requirements.

Swan, 279 F. Supp. 2d at 1222.

The Amended Complaint, however, simply proceeds from the flawed assumption that perfect compliance with the guidance was necessary to seek and receive hospice payments from Medicare, even though payment of claims that do not meet the guidelines is discretionary. Ex. A ("Coverage of hospice care for patients not meeting the criteria in this policy may be denied.") (emphasis added). The government provides no factual allegation to reasonably infer otherwise. The government's allegations consist of nothing more than a selective review of some unidentified criteria. See generally, Am. Compl. ¶¶ 193-94, 201, 204, 213, 236. The government then claims in conclusory fashion that each patient was ineligible based on that review. Id. As discussed above however, that narrow review does not support the government's leap to FCA liability – it does not sufficiently allege that the patients were ineligible (particularly fraudulently so) and, importantly, does not establish that such compliance was a condition of payment.

The certifications at issue on the Form 1450 in this case do not require the individual signer to inspect the patient's medical record and exhaustively compare the diagnosis or diagnoses establishing terminal prognosis against the guidance. See generally, Exs. C and D. In fact, the government has not alleged that any certification requirement or condition of payment requires this kind of undertaking. The Amended Complaint's only apparent basis is a comment from CMS in the Federal Register, which is a far cry from either a certification requirement or a condition of payment. Am. Compl. ¶ 35 (quoting 70 Fed. Reg. 70532, 70534-35 (Nov. 22. 2005)).

For example, the conditions of payment certified on Form 1450 have never required a certification that a patient meet disease-specific guidance. Exs. C and D. An unidentified representative of one of the unidentified Defendants certified to the best of his or her knowledge and belief that the claim was correct and complete, that records adequately disclosing services were maintained, and agreeing to furnish "necessary information. . . to such governmental agencies as required by applicable law." Id.

Even if these assurances could be taken to suggest that compliance with the particular provisions was a material condition, the government fails to allege actual non-compliance with the underlying provisions. A claim for payment certifies that the treatments or services were medically necessary, which here turns on the medical judgment of physicians. A Medicare patient is eligible for hospice if a hospice physician and the patient's attending physician determine, based on their clinical judgment, that the patient has a prognosis of six months or less if the disease runs its normal course. 42 U.S.C. §§ 1395f(a)(7)(A)(i), 1395x(dd)(3)(A); 42 C.F.R. § 418.22. The Amended Complaint does not allege that any determinations about the level of care or the admission and recertification decisions were not based on the reasonable

clinical judgment of the responsible physician or employee, or that physicians or employees knew or otherwise recklessly disregarded that the patients were in fact not terminal or otherwise inappropriate for the level of care.14 The government does not even sufficiently allege that the responsible physicians or employees did not believe that the medical records adequately supported their diagnosis of terminal illness. See also Ex. B (The disease-specific guidelines do "not mean, however, that meeting the guideline is required. The only requirement is that the documentation supports the beneficiary's prognosis of six months or less, if the illness runs its normal course.").

Instead, the government tries to rely on its own, incomplete and selective review of certain guidance to suggest that the medical records were incomplete and therefore lacked a basis to support the physician's clinical judgment that the patient has a terminal diagnosis. This strategy fails. Although, as of November 22, 2005, supra n.5, clinical information and other documentation that support the physician's medical prognosis must accompany the certification in the medical record, CMS has never required specific findings and in fact, rejected the use of the terms "specific" and "findings" to describe the supporting documentation. 70 Fed. Reg. 70532, 70543 (Nov. 22, 2005). Thus, it is the physician who determines what clinical information and other documentation is sufficient to support his clinical judgment. Even if the government's post hoc assessment of a patient's medical records against a given diagnosis under the applicable disease-specific guideline was correct, the Amended Complaint still does not

14 Under hospice regulations, the hospice interdisciplinary group is required to review and update the individualized plan of care for each patient at least every 15 calendar days, noting the patient's progress toward outcomes and goals specified in the plan of care. 42 C.F.R. § 418.56(d) (2008). This provides another level of review by a team including clinical professionals. There are no allegations that the patient's interdisciplinary group disagreed with the physician determinations that these patients were terminal and appropriate for the level of care being provided.

plausibly allege that the given patient was ineligible for hospice, particularly in light of the multiple physician certifications and the numerous exceptions recognized by CMS and Palmetto. Given that, the Amended Complaint does not plausibly allege how any of the alleged claims were false or fraudulent. The government consequently fails to establish that any of the alleged statutory or regulatory violations were conditions of Medicare payments and therefore has failed to allege any plausible basis for imposing FCA liability on any of the Defendants. For these reasons, the Amended Complaint must be dismissed.

B. The Amended Complaint Fails To Allege That Any Defendant Acted With The Requisite Scienter.

The Amended Complaint also should be dismissed because the government fails to allege another essential element of an FCA claim: that any of the Defendants knowingly submitted or caused to be submitted a false or fraudulent claim. The FCA requires that a false statement be made with actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of the information. United States ex rel. Joslin v. Community Home Health of Maryland, Inc., 984 F. Supp. 374, 384-85 (D. Md. 1997); Am. Compl. ¶ 20. To satisfy the FCA's scienter requirement, the government must allege, at a minimum, a "reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). "[I]t is important to remember that the standard for liability [under the FCA] is knowing, not negligent, presentation of a false claim." Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1053 (8th Cir. 2002) (internal citation omitted); see also Sealed Appellant I v. Sealed Appellee I, 156 F. App'x 630, 633 (5th Cir. 2005) (granting motion to dismiss because "Appellant has failed to plead any particular facts showing that Appellee was aware of the actions of its employees and intentionally filed false claims with the government. . . . The complaint includes no more than the conclusory assertions of Appellee's knowledge and intent to file fraudulent claims."); Hindo

v. University of Health Sciences/The Chicago Med. Sch., 65 F.3d 608, 613 (7th Cir. 1995) ("The requisite intent is the knowing presentation of what is known to be false. In short, the claim must be a lie.") (internal quotation and citations omitted). The government falls far short of meeting this standard, making only a passing reference that "Chemed and Vitas" knew that the conduct violated the FCA. See, e.g., Am. Compl. ¶ 68.

A complaint must identify specific culpable individuals to impute scienter to a corporation. [15] See Kushner, 317 F.3d at 827-830 (holding that the complaint's assertion that someone who may have been involved in the scheme "reported" to a corporate official is not specific enough to impute scienter to the corporation); Detroit Gen. Retirement Sys., 621 F.3d at 808 (holding that complaint alleging securities fraud against manufacturer failed to allege any one individual or group of individuals had all the pieces of information collectively at the time the allegedly misleading statements were made); In re Medtronic Inc., Secs. Litig., 618 F. Supp. 2d 1016, 1035 (D. Miss. 2009) (refusing to apply the "collective scienter" doctrine and requiring instead that the plaintiffs establish corporate scienter by adequately alleging the scienter of individual corporate officers). As discussed above, the Amended Complaint fails to allege who was involved in the purported FCA violations. The government references audits or reviews that

15 Although knowledge may be averred generally, the government still must plead a sufficient factual basis to give rise to a strong inference of fraudulent intent. "Essentially, while Rule 9(b) permits scienter to be demonstrated by inference, this must not be mistaken for license to base claims of fraud on speculation and conclusory allegations. An ample factual basis must be supplied to support the charges." Wood ex rel. United States v. Applied Research Associates, Inc., 328 F. App'x 744, 747 (2d Cir. 2009); see also Roop, 559 F.3d at 822 n.3 (quoting Allison Engine Co., 553 U.S. at 665) (plaintiff must show "that the defendant intended that the false record or statement be material to the government's decision to pay or approve the false claim"); United States ex rel. Lewis v. Walker, 2008 WL 2817091, at *3 (M.D. Ga. July 18, 2008) (quoting Watts v. Fla. Int'l Univ., 495 F.3d 1289, 1295-96 (11th Cir. 2007)) ("Even under the general notice pleading standard, however, Relators cannot simply generically recite the elements of their claim-i.e., that Defendant... 'knowingly caused to be submitted applications containing false and fabricated information and/or with reckless disregard of their falsity.'").

began in 2007, but similarly fails to allege who was involved in the audits, the purpose of the audits and if they involved review of claims (as opposed to medical records, which is all that is alleged), who received information about the audits, and what was done in response to the findings. Rather than plausibly suggesting some improper intent or knowledge, the fact that Vitas conducted such review is entirely consistent with a company training its employees in the law. The Amended Complaint simply fails to plead sufficient allegations showing that any Defendant knowingly submitted false claims to the government or knowingly created false records.

The only other allegations that the government relies on to establish scienter are that Vitas' continuous home care numbers were higher than the national average, and that Chemed and Vitas were aware that billing for continuous home care was excessive relative to other hospices. Am. Compl. ¶¶ 71-77. The government's suggestion that the "national average" is an accurate baseline is stunning given that as recently as May 3, 2013, the government issued a report that raised concern that hospices may not be "providing beneficiaries access to needed levels of care at the end of their lives," such as continuous home care. Ex. H (HHS Office of the Inspector General, Medicare Hospice: Use of General Inpatient Care 2 (2013), available at http://oig.hhs.gov/oei/reports/oei-02-10-00490.pdf). Specifically, the government "found that 953 hospices, or 27 percent of Medicare hospices, did not provide any GIP [general inpatient care] to Medicare beneficiaries in 2011 and that 429 of these hospices did not provide any level of hospice care other than routine home care" and that "[s]ixty-eight percent of hospices that did not provide GIP also did not provide continuous care . . . ." Id. at 2, 10. The government's findings suggest that nearly 20% of hospices do not provide continuous home care, significantly weighing down the national average while upwardly skewing the averages for hospices, like

Vitas, that comply with their obligations to provide all levels of care. Thus, the government's own findings and recommendations point to entirely proper reasons for Vitas' above-average continuous home care rates and the reason patients chose Vitas over other providers who were unwilling or unable to marshal the resources needed to provide other levels of care.

Thus, the government's failure to allege scienter additionally requires dismissal of the Amended Complaint under Rule 12(b)(6).

III. ANY CLAIMS PRIOR TO JULY 24, 2002 ARE BARRED BY THE APPLICABLE STATUTE OF LIMITATIONS.

A "motion to dismiss may be granted when a claim is barred under a statute of limitations." Varner v. Peterson Farms, 371 F.3d 1011, 1016 (8th Cir. 2004) (internal citation omitted). In its Amended Complaint, the government alleges that false claims were submitted or caused to be submitted "since at least 2002." Am. Compl. ¶ 9. From "the face of the complaint itself" it is therefore apparent that the government's claims began to accrue in 2002, if not earlier. Varner, 371 F.3d at 1016. Under the FCA, "[a] civil action under section 3730 may not be brought (1) more than 6 years after the date on which the violation of section 3729 is committed, or (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed, whichever occurs last." 31 U.S.C. § 3731(b).

Because the government did not file suit until May 2, 2013, some of its claims clearly are barred on the face of the Amended Complaint by the FCA's outer ten-year statute of limitations. The parties, however, entered into a tolling agreement involving the submission for payment to federal health care programs of hospice claims between July 24, 2002 and December 31, 2009,

and therefore Defendants seek dismissal on statute of limitations grounds only of claims submitted before July 24, 2002.

IV. THE UNJUST ENRICHMENT OR PAYMENT BY MISTAKE CLAIMS FAIL AS A MATTER OF LAW.

The government's common law claims of unjust enrichment16 and payment by mistake17 must be dismissed for essentially the same reasons that require dismissal of the FCA claims. Because there was nothing false or fraudulent about any alleged claims, Defendants were neither unjustly enriched nor paid by mistake. Moreover, the government's common law claims fail as a matter of law because the government has not adequately alleged which of the Defendants was mistakenly paid or unjustly enriched by the United States. Recovery cannot be obtained from someone who did not receive the excessive payment. Beeler v. Martin, 306 S.W.3d 108, 112–13 (Mo. Ct. App. 2010). Accordingly, the Amended Complaint fails to state a claim of unjust enrichment or payment by mistake upon which relief can be granted and should be dismissed in its entirety.

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16 To establish the elements of an unjust enrichment claim, the United States must prove that (1) it conferred a benefit on Defendants, (2) Defendants appreciated the benefit, and (3) Defendants accepted and retained the benefit under inequitable or unjust circumstances. Howard v. Turnbull, 316 S.W.3d 431, 436 (Mo. Ct. App. 2010) (citation omitted). "Unjust retention of benefits only occurs when the benefits were conferred (a) in misreliance on a right or duty; or (b) through dutiful intervention in another's affairs; or (c) under constraint." Id. (internal citations and quotation marks omitted). Even if a benefit is conferred and appreciated, if no injustice results from the retention of the benefit, then no cause of action for unjust enrichment will lie. Id.

17 Under Missouri law, "[o]ne who confers a benefit upon another due to a mistake is entitled to restitution." Homecomings Fin. Network, Inc. v. Brown, 343 S.W.3d 681, 685 (Mo. Ct. App. 2011) (citation omitted). To state a cause of action for payment under mistake of fact, the United States must allege: (1) that it paid the Defendants; (2) that it was mistaken as to a fact; (3) that but for its mistake of fact, it would not have paid; (4) that the government was under no legal obligation to pay; and (5) that it is entitled to restitution for the amounts paid. Western Casualty & Sur. Co. v. Kohm, 638 S.W.2d 798, 800 (Mo. Ct. App. 1982).

CONCLUSION

For all of the foregoing reasons, the Court should grant Defendants' motion to dismiss the Amended Complaint with prejudice.

Respectfully submitted,

/s/ William A. Lynch
William A. Lynch #25006
Stacey M. Bowman #60778
HUSCH BLACKWELL LLP
4801 Main Street, Suite 1000
Kansas City, Missouri 64112
Phone: 816-983-8000
Fax: 816-983-8080
william.lynch@huschblackwell.com
stacey.bowman@huschblackwell.com

Harvey M. Tettlebaum #20005
Barbara L. Miltenberger #36635
HUSCH BLACKWELL LLP
235 East High Street, Suite 200
P. O. Box 1251
Jefferson City, Missouri 65101
Phone: 573-635-9118
Fax: 573-634-7854
harvey.tettlebaum@huschblackwell.com
barbara.miltenberger@huschblackwell.com

Peter S. Spivack *Pro Hac Vice*
HOGAN LOVELLS US LLP
555 13th Street, NW
Washington, DC 20004-1109
Phone: 202-637-5600
Fax: 202-637-5910
peter.spivack@hoganlovells.com

Stephanie L. Carman *Pro Hac Vice*
HOGAN LOVELLS US LLP
600 Brickell Avenue, 27th Floor
Miami, Florida 33131
Phone: 305-459-6500
Fax: 305-459-6550

stephanie.carman@hoganlovells.com

Attorneys for Defendants

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 24th day of September 2013, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I further certify that a true copy of the foregoing was furnished by CM/ECF to all counsel of record.

/s/ William A. Lynch